

110TH CONGRESS
2D SESSION

S. 3408

To amend title XI of the Social Security Act to provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Comparative Effectiveness Research Trust Fund, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JULY 31, 2008

Mr. BAUCUS (for himself and Mr. CONRAD) introduced the following bill;
which was read twice and referred to the Committee on Finance

A BILL

To amend title XI of the Social Security Act to provide for the conduct of comparative effectiveness research and to amend the Internal Revenue Code of 1986 to establish a Comparative Effectiveness Research Trust Fund, and for other purposes.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

3 **SECTION 1. SHORT TITLE.**

4 This Act may be cited as the “Comparative Effective-
5 ness Research Act of 2008”.

1 **SEC. 2. COMPARATIVE EFFECTIVENESS RESEARCH.**

2 (a) IN GENERAL.—Title XI of the Social Security Act
3 (42 U.S.C. 1301 et seq.) is amended by adding at the end
4 the following new part:

5 “PART D—COMPARATIVE EFFECTIVENESS RESEARCH

6 “COMPARATIVE EFFECTIVENESS RESEARCH

7 “SEC. 1181. (a) DEFINITIONS.—In this section:

8 “(1) BOARD.—The term ‘Board’ means the
9 Board of Governors established under subsection (f).

10 “(2) COMPARATIVE CLINICAL EFFECTIVENESS
11 RESEARCH.—

12 “(A) IN GENERAL.—The term ‘compara-
13 tive clinical effectiveness research’ means re-
14 search evaluating and comparing the clinical ef-
15 fectiveness, risks, and benefits of 2 or more
16 medical treatments, services, and items de-
17 scribed in subparagraph (B).

18 “(B) MEDICAL TREATMENTS, SERVICES,
19 AND ITEMS DESCRIBED.—The medical treat-
20 ments, services, and items described in this sub-
21 paragraph are health care interventions, proto-
22 cols for treatment, procedures, medical devices,
23 diagnostic tools, pharmaceuticals (including
24 drugs and biologicals), and any other processes
25 or items being used in the treatment and diag-

1 nosis of, or prevention of illness or injury in,
2 patients.

3 “(3) COMPARATIVE EFFECTIVENESS RE-
4 SEARCH.—The term ‘comparative effectiveness re-
5 search’ means research evaluating and comparing
6 the implications and outcomes of 2 or more health
7 care strategies to address a particular medical condi-
8 tion.

9 “(4) CONFLICTS OF INTEREST.—The term
10 ‘conflicts of interest’ means associations, including
11 financial and personal, that may be reasonably as-
12 sumed to have the potential to bias an individual’s
13 decisions in matters related to the Institute or the
14 conduct of activities under this section.

15 “(5) INSTITUTE.—The term ‘Institute’ means
16 the ‘Health Care Comparative Effectiveness Re-
17 search Institute’ established under subsection (b)(1).

18 “(b) HEALTH CARE COMPARATIVE EFFECTIVENESS
19 RESEARCH INSTITUTE.—

20 “(1) ESTABLISHMENT.—There is authorized to
21 be established a nonprofit corporation, to be known
22 as the “Health Care Comparative Effectiveness Re-
23 search Institute” which is neither an agency nor es-
24 tablishment of the United States Government.

1 “(2) APPLICATION OF PROVISIONS.—The Insti-
2 tute shall be subject to the provisions of this section,
3 and, to the extent consistent with this section, to the
4 District of Columbia Nonprofit Corporation Act.

5 “(3) FUNDING OF COMPARATIVE EFFECTIVE-
6 NESS RESEARCH.—For fiscal year 2009 and each
7 subsequent fiscal year, amounts in the Comparative
8 Effectiveness Research Trust Fund (referred to in
9 this section as the ‘CERTF’) under section 9511 of
10 the Internal Revenue Code of 1986 shall be avail-
11 able, without further appropriation, to the Institute
12 to carry out this section.

13 “(c) PURPOSE.—The purpose of the Institute is to
14 improve health care delivered to individuals in the United
15 States by advancing the quality and thoroughness of evi-
16 dence concerning the manner in which diseases, disorders,
17 and other health conditions can effectively and appro-
18 priately be prevented, diagnosed, treated, and managed
19 clinically through research and evidence synthesis, and the
20 dissemination of research findings with respect to the rel-
21 ative outcomes, effectiveness, and appropriateness of the
22 medical treatments, services, and items described in sub-
23 section (a)(2)(B).

24 “(d) DUTIES.—

1 “(1) IDENTIFYING RESEARCH PRIORITIES AND
2 ESTABLISHING RESEARCH PROJECT AGENDA.—

3 “(A) IDENTIFYING RESEARCH PRIOR-
4 ITIES.—The Institute shall identify national
5 priorities for comparative clinical effectiveness
6 research, taking into account factors, includ-
7 ing—

8 “(i) disease incidence, prevalence, and
9 burden in the United States;

10 “(ii) evidence gaps in terms of clinical
11 outcomes;

12 “(iii) practice variations, including
13 variations in delivery and outcomes by ge-
14 ography, treatment site, provider type, and
15 patient subgroup;

16 “(iv) the potential for new evidence
17 concerning certain categories of health care
18 services or treatments to improve patient
19 health and well-being, and the quality of
20 care; and

21 “(v) the effect or potential for an ef-
22 fect on health expenditures associated with
23 a health condition or the use of a par-
24 ticular medical treatment, service, or item.

1 “(B) ESTABLISHING RESEARCH PROJECT
2 AGENDA.—

3 “(i) IN GENERAL.—The Institute shall
4 establish and update a research project
5 agenda to address the priorities identified
6 under subparagraph (A), taking into con-
7 sideration the types of research that might
8 address each priority and the relative value
9 (determined based on the cost of con-
10 ducting such research compared to the po-
11 tential usefulness of the information pro-
12 duced by such research) associated with
13 such different types of research, and such
14 other factors as the Institute determines
15 appropriate.

16 “(ii) CONSIDERATION OF NEED TO
17 CONDUCT A SYSTEMATIC REVIEW.—In es-
18 tablishing and updating the research
19 project agenda under clause (i), the Insti-
20 tute shall consider the need to conduct a
21 systematic review of existing research be-
22 fore providing for the conduct of new re-
23 search under paragraph (2)(A).

24 “(2) CARRYING OUT RESEARCH PROJECT AGEN-
25 DA.—

1 “(A) COMPARATIVE CLINICAL EFFECTIVE-
2 NESS RESEARCH.—In carrying out the research
3 project agenda established under paragraph
4 (1)(B), the Institute shall provide for the con-
5 duct of appropriate research and the synthesis
6 of evidence, in accordance with the methodo-
7 logical standards adopted under paragraph (9),
8 using methods, including the following:

9 “(i) Systematic reviews and assess-
10 ments of existing research and evidence.

11 “(ii) Clinical research, such as ran-
12 domized controlled trials and observational
13 studies.

14 “(iii) Any other methodologies rec-
15 ommended by the methodology committee
16 established under paragraph (6) that are
17 adopted by the Board under paragraph
18 (9).

19 “(B)(i) CONTRACTS WITH FEDERAL AGEN-
20 CIES AND INSTRUMENTALITIES.—The Institute
21 shall give preference to agencies and instrumen-
22 talities of the Federal Government that have ex-
23 perience in conducting comparative clinical ef-
24 fectiveness research, such as the Agency for
25 Healthcare Research and Quality, when enter-

ing into contracts for the management and conduct of research in accordance with the research project agenda established under paragraph (1)(B), to the extent that such contracts are authorized under the governing statutes of such agencies and instrumentalities.

“(ii) CONTRACTS WITH OTHER ENTITIES.—The Institute may enter into contracts with appropriate private sector research or study-conducting entities for the conduct of research described in clause (i).

“(iii) CONDITIONS FOR CONTRACTS.—A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

“(I) abide by the transparency and conflicts of interest requirements that apply to the Institute with respect to the research managed or conducted under such contract;

“(II) comply with the methodological standards adopted under paragraph (9) with respect to such research; and

“(III) take into consideration public comments on the study design that are

transmitted by the Institute to the agency, instrumentality, or other entity under subsection (i)(1)(B) during the finalization of the study design and transmit responses to such comments to the Institute, which will publish such comments, responses, and finalized study design in accordance with subsection (i)(3)(A)(iii) prior to the conduct of such research.

“(iv) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or co-insurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

“(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis, in order to take into account new research and evolving evidence as they become available, as appropriate.

“(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall—

1 “(i) be designed, as appropriate, to
2 take into account the potential for dif-
3 ferences in the effectiveness of health care
4 treatments, services, and items as used
5 with various subpopulations, such as racial
6 and ethnic minorities, women, different age
7 groups, and individuals with different
8 comorbidities; and

9 “(ii) seek to include members of such
10 subpopulations as subjects in the research
11 as feasible and appropriate.

12 “(3) STUDY AND REPORT ON FEASIBILITY OF
13 CONDUCTING RESEARCH IN-HOUSE.—

14 “(A) STUDY.—The Institute shall conduct
15 a study on the feasibility of conducting research
16 in-house.

17 “(B) REPORT.—Not later than 5 years
18 after the date of enactment of this section, the
19 Institute shall submit a report to Congress con-
20 taining the results of the study conducted under
21 subparagraph (A).

22 “(4) DATA COLLECTION.—

23 “(A) IN GENERAL.—The Secretary shall,
24 with appropriate safeguards for privacy, make
25 available to the Institute such data collected by

1 the Centers for Medicare & Medicaid Services
2 under the programs under titles XVIII, XIX,
3 and XXI as the Institute may require to carry
4 out this section. The Institute may also request
5 and, if such request is granted, obtain data
6 from Federal, State, or private entities.

7 “(B) USE OF DATA.—The Institute shall
8 only use data provided to the Institute under
9 subparagraph (A) in accordance with laws and
10 regulations governing the release and use of
11 such data, including applicable confidentiality
12 and privacy standards.

13 “(5) APPOINTING ADVISORY PANELS.—

14 “(A) IN GENERAL.—The Institute may ap-
15 point permanent or ad hoc advisory panels as
16 determined appropriate by the Institute to as-
17 sist in the establishment and carrying out of
18 the research project agenda under paragraphs
19 (1) and (2), respectively. Panels may advise or
20 guide the Institute in matters such as identi-
21 fying gaps in and updating medical evidence
22 and identifying research priorities and potential
23 study designs in order to ensure that the infor-
24 mation produced from such research is clinically
25 relevant to decisions made by clinicians and pa-

1 tients at the point of care and may provide ad-
2 vice throughout the conduct of research.

3 “(B) COMPOSITION.—An advisory panel
4 appointed under subparagraph (A) shall include
5 representatives of clinicians and patients and
6 may include experts in scientific and health
7 services research, health services delivery, and
8 the manufacture of health items who have expe-
9 rience in the relevant topic, project, or category
10 for which the panel is established.

11 “(6) ESTABLISHING METHODOLOGY COM-
12 MITTEE.—

13 “(A) IN GENERAL.—The Institute shall es-
14 tablish a standing methodology committee to
15 carry out the functions described in subpara-
16 graph (C).

17 “(B) APPOINTMENT AND COMPOSITION.—
18 Members shall be appointed to the methodology
19 committee established under subparagraph (A)
20 by the Comptroller General of the United
21 States. Members appointed to the methodology
22 committee shall be experts in their scientific
23 field, such as health services research, clinical
24 research, comparative effectiveness research,
25 biostatistics, and research methodologies.

1 Stakeholders with such expertise may be ap-
2 pointed to the methodology committee.

3 “(C) FUNCTIONS.—Subject to subpara-
4 graph (D), the methodology committee shall
5 work to develop and improve the science of
6 comparative effectiveness research by under-
7 taking the following activities:

8 “(i) Not later than 1 year after the
9 date on which the members of the method-
10 ology committee are appointed under sub-
11 paragraph (B), developing and periodically
12 updating methodological standards regard-
13 ing outcomes measures, risk adjustment,
14 statistical protocols, evaluation of evidence,
15 conduct of research, and other aspects of
16 research and assessment to be used when
17 conducting research on comparative clinical
18 effectiveness (and procedures for the use of
19 such standards) in order to help ensure ac-
20 curate and effective comparisons. Such
21 standards shall also include methods by
22 which new information, data, or advances
23 in technology are considered and incor-
24 porated into ongoing research projects by
25 the Institute, as appropriate. In developing

1 and updating methodological standards
 2 under this clause, the methodology com-
 3 mittee shall ensure that such standards are
 4 scientifically based.

5 “(ii) Not later than 5 years after such
 6 date, examining the following:

7 “(I) Methods by which various
 8 aspects of the health care delivery sys-
 9 tem (such as benefit design and per-
 10 formance, and health services organi-
 11 zation, management, and delivery)
 12 could be assessed and compared for
 13 their relative effectiveness, benefits,
 14 risks, advantages, and disadvantages
 15 in a scientifically valid and standard-
 16 ized way.

17 “(II) Methods by which cost-ef-
 18 fectiveness and value could be as-
 19 sessed in a scientifically valid and
 20 standardized way.

21 “(D) CONSULTATION AND CONDUCT OF
 22 EXAMINATIONS.—

23 “(i) IN GENERAL.—Subject to clause
 24 (iii), in undertaking the activities described

in subparagraph (C), the methodology committee shall—

“(I) consult or contract with 1 or more of the entities described in clause (ii); and

“(II) consult with stakeholders and other entities knowledgeable in relevant fields, as appropriate.

“(ii) ENTITIES DESCRIBED.—The following entities are described in this clause:

“(I) The Institute of Medicine of the National Academies.

“(II) The Agency for Healthcare Research and Quality.

“(III) The National Institutes of Health.

“(iii) CONDUCT OF EXAMINATIONS.—The methodology committee shall contract with the Institute of Medicine of the National Academies for the conduct of the examinations described in subclauses (I) and (II) of subparagraph (C)(ii).

“(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee’s performance of the functions de-

1 scribed in subparagraph (C). Reports submitted
2 under the preceding sentence with respect to
3 the functions described in clause (i) of such
4 subparagraph shall contain recommendations—

5 “(i) for the Institute to adopt meth-
6 odological standards developed and up-
7 dated by the methodology committee under
8 such subparagraph; and

9 “(ii) for such other action as the
10 methodology committee determines is nec-
11 essary to comply with such methodological
12 standards.

13 “(7) PROVIDING FOR A PEER-REVIEW PROC-
14 ESS.—

15 “(A) IN GENERAL.—The Institute shall en-
16 sure that there is a process for peer review of
17 the research conducted under this section.
18 Under such process—

19 “(i) evidence from research conducted
20 under this section shall be reviewed to as-
21 sess scientific integrity and adherence to
22 methodological standards adopted under
23 paragraph (9); and

24 “(ii) a list of the names of individuals
25 contributing to any peer-review process

1 during the preceding year or years shall be
2 made public and included in annual reports
3 in accordance with paragraph (11)(D).

4 “(B) COMPOSITION.—Such peer-review
5 process shall have been designed in a manner so
6 as to avoid bias and conflicts of interest on the
7 part of the reviewers and shall be composed of
8 experts in the scientific field relevant to the re-
9 search under review.

10 “(C) USE OF EXISTING PROCESSES.—In
11 the case where the Institute enters into a con-
12 tract or other agreement with another entity for
13 the conduct or management of research under
14 this section, the Institute may utilize the peer-
15 review process of such entity if such process
16 meets the requirements under subparagraphs
17 (A) and (B).

18 “(8) DISSEMINATION OF RESEARCH FIND-
19 INGS.—

20 “(A) IN GENERAL.—The Institute shall
21 disseminate research findings to clinicians, pa-
22 tients, and the general public in accordance
23 with the dissemination protocols and strategies
24 adopted under paragraph (9). Research findings
25 disseminated—

1 “(i) shall convey findings of research
2 so that they are comprehensible and useful
3 to patients and providers in making health
4 care decisions;

5 “(ii) shall discuss findings and other
6 considerations specific to certain sub-
7 populations, risk factors, and
8 comorbidities, as appropriate;

9 “(iii) shall include considerations such
10 as limitations of research and what further
11 research may be needed, as appropriate;

12 “(iv) shall not include practice guide-
13 lines or policy recommendations; and

14 “(v) shall not include any data the
15 dissemination of which would violate the
16 privacy of research participants or violate
17 any confidentiality agreements made with
18 respect to the use of data under this sec-
19 tion.

20 “(B) DISSEMINATION PROTOCOLS AND
21 STRATEGIES.—The Institute shall develop pro-
22 tocols and strategies for the appropriate dis-
23 semination of research findings in order to en-
24 sure effective communication of such findings
25 and the use and incorporation of such findings

1 into relevant activities for the purpose of in-
2 forming higher quality and more effective and
3 efficient decisions regarding medical treat-
4 ments, services, and items. In developing and
5 adopting such protocols and strategies, the In-
6 stitute shall consult with stakeholders con-
7 cerning the types of dissemination that will be
8 most useful to the end users of the information
9 and may provide for the utilization of multiple
10 formats for conveying findings to different audi-
11 ences.

12 “(C) DEFINITION OF RESEARCH FIND-
13 INGS.—In this paragraph, the term ‘research
14 findings’ means the results of a study, ap-
15 praisal, or assessment.

16 “(9) ADOPTION.—Subject to subsection
17 (i)(1)(A)(i), the Institute shall adopt the national
18 priorities identified under paragraph (1)(A), the re-
19 search project agenda established under paragraph
20 (1)(B), the methodological standards developed and
21 updated by the methodology committee under para-
22 graph (6)(C)(i), any peer-review process provided
23 under paragraph (7), and dissemination protocols
24 and strategies developed under paragraph (8)(B) by
25 majority vote. In the case where the Institute does

1 not adopt such national priorities, research project
 2 agenda, methodological standards, peer-review proc-
 3 ess, or dissemination protocols and strategies in ac-
 4 cordance with the preceding sentence, the national
 5 priorities, research project agenda, methodological
 6 standards, peer-review process, or dissemination pro-
 7 tocols and strategies shall be referred to the appro-
 8 priate staff or entity within the Institute (or, in the
 9 case of the methodological standards, the method-
 10 ology committee) for further review.

11 “(10) COORDINATION OF RESEARCH AND RE-
 12 SOURCES AND BUILDING CAPACITY FOR RE-
 13 SEARCH.—

14 “(A) COORDINATION OF RESEARCH AND
 15 RESOURCES.—The Institute shall coordinate re-
 16 search conducted, commissioned, or otherwise
 17 funded under this section with comparative clin-
 18 ical effectiveness and other relevant research
 19 and related efforts conducted by public and pri-
 20 vate agencies and organizations in order to en-
 21 sure the most efficient use of the Institute’s re-
 22 sources and that research is not duplicated un-
 23 necessarily.

24 “(B) BUILDING CAPACITY FOR RE-
 25 SEARCH.—The Institute may build capacity for

1 comparative clinical effectiveness research and
2 other relevant research and related efforts
3 through appropriate activities, such as making
4 payments, up to 5 percent of the amounts ap-
5 propriated or credited to the CERTF under
6 section 9511(b) of the Internal Revenue Code
7 of 1986 with respect to the fiscal year, to The
8 Cochrane Collaboration (or a successor organi-
9 zation) to support the infrastructure of The
10 Cochrane Collaboration (or a successor organi-
11 zation) or to provide for sets of reviews related
12 to a particular topic or associated with a par-
13 ticular review group.

14 “(C) INCLUSION IN ANNUAL REPORTS.—

15 The Institute shall report on any coordination
16 and capacity building conducted under this
17 paragraph in annual reports in accordance with
18 paragraph (11)(E).

19 “(11) ANNUAL REPORTS.—The Institute shall
20 submit an annual report to Congress and the Presi-
21 dent, and shall make the annual report available to
22 the public. Such report shall contain—

23 “(A) a description of the activities con-
24 ducted under this section during the preceding
25 year, including the use of amounts appropriated

1 or credited to the CERTF under section
2 9511(b) of the Internal Revenue Code of 1986
3 to carry out this section, research projects com-
4 pleted and underway, and a summary of the
5 findings of such projects;

6 “(B) the research project agenda and
7 budget of the Institute for the following year;

8 “(C) a description of research priorities
9 identified under paragraph (1)(A), dissemina-
10 tion protocols and strategies developed by the
11 Institute under paragraph (8)(B), and meth-
12 odological standards developed and updated by
13 the methodology committee under paragraph
14 (6)(C)(i) that are adopted under paragraph (9)
15 during the preceding year;

16 “(D) the names of individuals contributing
17 to any peer-review process provided under para-
18 graph (7) during the preceding year or years, in
19 a manner such that those individuals cannot be
20 identified with a particular research project;
21 and

22 “(E) a description of efforts by the Insti-
23 tute under paragraph (10) to—

24 “(i) coordinate the research con-
25 ducted, commissioned, or otherwise funded

1 under this section and the resources of the
2 Institute with research and related efforts
3 conducted by other private and public enti-
4 ties; and

5 “(ii) build capacity for comparative
6 clinical effectiveness research and other
7 relevant research and related efforts
8 through appropriate activities.

9 “(F) any other relevant information (in-
10 cluding information on the membership of the
11 Board, advisory panels appointed under para-
12 graph (5), the methodology committee estab-
13 lished under paragraph (6), and the executive
14 staff of the Institute, any conflicts of interest
15 with respect to the members of such Board, ad-
16 visory panels, and methodology committee, or
17 with respect to any individuals selected for em-
18 ployment as executive staff of the Institute, and
19 any bylaws adopted by the Board during the
20 preceding year).

21 “(e) ADMINISTRATION.—

22 “(1) IN GENERAL.—Subject to paragraph (2),
23 the Board shall carry out the duties of the Institute.

1 “(2) NONDELEGABLE DUTIES.—The activities
2 described in subsections (b)(3)(D), (d)(1), and
3 (d)(9) are nondelegable.

4 “(f) BOARD OF GOVERNORS.—

5 “(1) IN GENERAL.—The Institute shall have a
6 Board of Governors, which shall consist of the fol-
7 lowing members:

8 “(A) The Secretary of Health and Human
9 Services (or the Secretary’s designee).

10 “(B) The Director of the Agency for
11 Healthcare Research and Quality (or the Direc-
12 tor’s designee).

13 “(C) The Director of the National Insti-
14 tutes of Health (or the Director’s designee).

15 “(D) 18 members appointed by the Comp-
16 troller General of the United States not later
17 than 6 months after the date of enactment of
18 this section, as follows:

19 “(i) 3 members representing patients
20 and health care consumers.

21 “(ii) 3 members representing prac-
22 ticing physicians, including surgeons.

23 “(iii) 3 members representing agen-
24 cies that administer public programs, as
25 follows:

1 “(I) 1 member representing the
2 Centers for Medicare & Medicaid
3 Services who has experience in admin-
4 istering the program under title
5 XVIII.

6 “(II) 1 member representing
7 agencies that administer State health
8 programs (who may represent the
9 Centers for Medicare & Medicaid
10 Services and have experience in ad-
11 ministering the program under title
12 XIX or the program under title XXI
13 or be a governor of a State).

14 “(III) 1 member representing
15 agencies that administer other Fed-
16 eral health programs (such as a
17 health program of the Department of
18 Defense under chapter 55 of title 10,
19 United States Code, the Federal em-
20 ployees health benefits program under
21 chapter 89 of title 5 of such Code, a
22 health program of the Department of
23 Veterans Affairs under chapter 17 of
24 title 38 of such Code, or a medical

1 care program of the Indian Health
2 Service or of a tribal organization).

3 “(iv) 3 members representing private
4 payers, of whom at least 1 member shall
5 represent health insurance issuers and at
6 least 1 member shall represent employers
7 who self-insure employee benefits.

8 “(v) 3 members representing pharma-
9 ceutical, device, and technology manufac-
10 turers or developers.

11 “(vi) 1 member representing nonprofit
12 organizations involved in health services re-
13 search.

14 “(vii) 1 member representing organi-
15 zations that focus on quality measurement
16 and improvement or decision support.

17 “(viii) 1 member representing inde-
18 pendent health services researchers.

19 “(2) QUALIFICATIONS.—

20 “(A) DIVERSE REPRESENTATION OF PER-
21 SPECTIVES.—The Board shall represent a broad
22 range of perspectives and collectively have sci-
23 entific expertise in clinical health sciences re-
24 search, including epidemiology, decisions
25 sciences, health economics, and statistics.

1 “(B) CONFLICTS OF INTEREST.—

2 “(i) IN GENERAL.—In appointing
3 members of the Board under paragraph
4 (1)(D), the Comptroller General of the
5 United States shall take into consideration
6 any conflicts of interest of potential ap-
7 pointees. Any conflicts of interest of mem-
8 bers appointed to the Board under para-
9 graph (1) shall be disclosed in accordance
10 with subsection (i)(4)(B).

11 “(ii) RECUSAL.—A member of the
12 Board shall be recused from participating
13 with respect to a particular research
14 project or other matter considered by the
15 Board in carrying out its research project
16 agenda under subsection (d)(2) in the case
17 where the member (or an immediate family
18 member of such member) has a financial
19 or personal interest directly related to the
20 research project or the matter that could
21 affect or be affected by such participation.

22 “(3) TERMS.—

23 “(A) IN GENERAL.—A member of the
24 Board appointed under paragraph (1)(D) shall
25 be appointed for a term of 6 years, except with

1 respect to the members first appointed under
2 such paragraph—

3 “(i) 6 shall be appointed for a term of
4 6 years;

5 “(ii) 6 shall be appointed for a term
6 of 4 years; and

7 “(iii) 6 shall be appointed for a term
8 of 2 years.

9 “(B) LIMITATION.—No individual shall be
10 appointed to the Board under paragraph (1)(D)
11 for more than 2 terms.

12 “(C) EXPIRATION OF TERM.—Any member
13 of the Board whose term has expired may serve
14 until such member’s successor has taken office,
15 or until the end of the calendar year in which
16 such member’s term has expired, whichever is
17 earlier.

18 “(D) VACANCIES.—

19 “(i) IN GENERAL.—Any member ap-
20 pointed to fill a vacancy prior to the expi-
21 ration of the term for which such mem-
22 ber’s predecessor was appointed shall be
23 appointed for the remainder of such term.

24 “(ii) VACANCIES NOT TO AFFECT
25 POWER OF BOARD.—A vacancy on the

1 Board shall not affect its powers, but shall
2 be filled in the same manner as the origi-
3 nal appointment was made.

4 “(4) CHAIRPERSON AND VICE-CHAIRPERSON.—

5 “(A) IN GENERAL.—The Comptroller Gen-
6 eral of the United States shall designate a
7 Chairperson and Vice-Chairperson of the Board
8 from among the members of the Board ap-
9 pointed under paragraph (1)(D).

10 “(B) TERM.—The members so designated
11 shall serve as Chairperson and Vice-Chair-
12 person of the Board for a period of 3 years.

13 “(5) COMPENSATION.—

14 “(A) IN GENERAL.—A member of the
15 Board shall be entitled to compensation at the
16 per diem equivalent of the rate provided for
17 level IV of the Executive Schedule under section
18 5315 of title 5, United States Code.

19 “(B) TRAVEL EXPENSES.—While away
20 from home or regular place of business in the
21 performance of duties for the Board, each mem-
22 ber of the Board may receive reasonable travel,
23 subsistence, and other necessary expenses.

24 “(6) DIRECTOR AND STAFF; EXPERTS AND
25 CONSULTANTS.—The Board may—

1 “(A) employ and fix the compensation of
2 an executive director and such other personnel
3 as may be necessary to carry out the duties of
4 the Institute;

5 “(B) seek such assistance and support as
6 may be required in the performance of the du-
7 ties of the Institute from appropriate depart-
8 ments and agencies of the Federal Government;

9 “(C) enter into contracts or make other ar-
10 rangements and make such payments as may
11 be necessary for performance of the duties of
12 the Institute;

13 “(D) provide travel, subsistence, and per
14 diem compensation for individuals performing
15 the duties of the Institute, including members
16 of any advisory panel appointed under sub-
17 section (d)(5), members of the methodology
18 committee established under subsection (d)(6),
19 and individuals selected to contribute to any
20 peer-review process under subsection (d)(7);
21 and

22 “(E) prescribe such rules, regulations, and
23 bylaws as the Board determines necessary with
24 respect to the internal organization and oper-
25 ation of the Institute.

1 “(7) MEETINGS AND HEARINGS.—The Board
2 shall meet and hold hearings at the call of the
3 Chairperson or a majority of its members. In the
4 case where the Board is meeting on matters not re-
5 lated to personnel, Board meetings shall be open to
6 the public and advertised.

7 “(8) QUORUM.—A majority of the members of
8 the Board shall constitute a quorum for purposes of
9 conducting the duties of the Institute, but a lesser
10 number of members may meet and hold hearings.

11 “(g) FINANCIAL OVERSIGHT.—

12 “(1) CONTRACT FOR AUDIT.—The Institute
13 shall provide for the conduct of financial audits of
14 the Institute on an annual basis by a private entity
15 with expertise in conducting financial audits.

16 “(2) REVIEW OF AUDIT AND REPORT TO CON-
17 GRESS.—The Comptroller General of the United
18 States shall—

19 “(A) review the results of the audits con-
20 ducted under paragraph (1); and

21 “(B) submit a report to Congress con-
22 taining the results of such audits and review.

23 “(h) GOVERNMENTAL OVERSIGHT.—

24 “(1) REVIEW AND REPORTS.—

1 “(A) IN GENERAL.—The Comptroller Gen-
2 eral of the United States shall review the fol-
3 lowing:

4 “(i) Processes established by the In-
5 stitute, including those with respect to the
6 identification of research priorities under
7 subsection (d)(1)(A) and the conduct of re-
8 search projects under this section. Such re-
9 view shall determine whether information
10 produced by such research projects—

11 “(I) is objective and credible;

12 “(II) is produced in a manner
13 consistent with the requirements
14 under this section; and

15 “(III) is developed through a
16 transparent process.

17 “(ii) The overall effect of the Institute
18 and the effectiveness of activities con-
19 ducted under this section, including an as-
20 sessment of—

21 “(I) the utilization of the find-
22 ings of research conducted under this
23 section by health care decision mak-
24 ers; and

1 “(II) the effect of the Institute
2 and such activities on innovation and
3 on the health economy of the United
4 States.

5 “(B) REPORTS.—Not later than 5 years
6 after the date of enactment of this section, and
7 not less frequently than every 5 years there-
8 after, the Comptroller General of the United
9 States shall submit a report to Congress con-
10 taining the results of the review conducted
11 under subparagraph (A), together with rec-
12 ommendations for such legislation and adminis-
13 trative action as the Comptroller General deter-
14 mines appropriate.

15 “(2) FUNDING ASSESSMENT.—

16 “(A) IN GENERAL.—The Comptroller Gen-
17 eral of the United States shall assess the ade-
18 quacy and use of funding for the Institute and
19 activities conducted under this section under
20 the CERTF under section 9511 of the Internal
21 Revenue Code of 1986. Such assessment shall
22 include a determination as to whether, based on
23 the utilization of findings by public and private
24 payers, each of the following are appropriate
25 sources of funding for the Institute, including a

1 determination of whether such sources of fund-
2 ing should be continued or adjusted:

3 “(i) The transfer of funds from the
4 Federal Hospital Insurance Trust Fund
5 under section 1817 and the Federal Sup-
6 plementary Medical Insurance Trust Fund
7 under section 1841 to the CERTF under
8 section 1182.

9 “(ii) The amounts appropriated under
10 subparagraphs (A), (B), (C), (D)(ii), and
11 (E)(ii) of subsection (b)(1) of such section
12 9511.

13 “(iii) Private sector contributions
14 under subparagraphs (D)(i) and (E)(i) of
15 such subsection (b)(1).

16 “(B) REPORT.—Not later than 8 years
17 after the date of enactment of this section, the
18 Comptroller General of the United States shall
19 submit a report to Congress containing the re-
20 sults of the assessment conducted under sub-
21 paragraph (A), together with recommendations
22 for such legislation and administrative action as
23 the Comptroller General determines appro-
24 priate.

1 “(i) ENSURING TRANSPARENCY, CREDIBILITY, AND
2 ACCESS.—The Institute shall establish procedures to en-
3 sure that the following requirements for ensuring trans-
4 parency, credibility, and access are met:

5 “(1) PUBLIC COMMENT PERIODS.—

6 “(A) IN GENERAL.—The Institute shall
7 provide for a public comment period of not less
8 than 30 and not more than 60 days at the fol-
9 lowing times:

10 “(i) Prior to the adoption of the na-
11 tional priorities identified under subsection
12 (d)(1)(A), the research project agenda es-
13 tablished under subsection (d)(1)(B), the
14 methodological standards developed and
15 updated by the methodology committee
16 under subsection (d)(6)(C)(i), the peer-re-
17 view process generally provided under sub-
18 section (d)(7), and dissemination protocols
19 and strategies developed by the Institute
20 under subsection (d)(8)(B) in accordance
21 with subsection (d)(9).

22 “(ii) Prior to the finalization of indi-
23 vidual study designs.

24 “(B) TRANSMISSION OF PUBLIC COM-
25 MENTS ON STUDY DESIGN.—The Institute shall

1 transmit public comments submitted during the
2 public comment period described in subpara-
3 graph (A)(ii) to the entity conducting research
4 with respect to which the individual study de-
5 sign is being finalized.

6 “(2) ADDITIONAL FORUMS.—The Institute
7 shall, in addition to the public comment periods de-
8 scribed in paragraph (1)(A), support forums to in-
9 crease public awareness and obtain and incorporate
10 public feedback through media (such as an Internet
11 website) on the following:

12 “(A) The identification of research prior-
13 ities and the establishment of the research
14 project agenda under subparagraphs (A) and
15 (B), respectively, of subsection (d)(1).

16 “(B) Research findings.

17 “(C) Any other duties, activities, or proc-
18 esses the Institute determines appropriate.

19 “(3) PUBLIC AVAILABILITY.—The Institute
20 shall make available to the public and disclose
21 through the official public Internet website of the In-
22 stitute, and through other forums and media the In-
23 stitute determines appropriate, the following:

24 “(A) The process and methods for the con-
25 duct of research under this section, including—

1 “(i) the identity of the entity con-
2 ducting such research;

3 “(ii) any links the entity has to indus-
4 try (including such links that are not di-
5 rectly tied to the particular research being
6 conducted under this section);

7 “(iii) draft study designs (including
8 research questions and the finalized study
9 design, together with public comments on
10 such study design and responses to such
11 comments);

12 “(iv) research protocols (including
13 measures taken, methods of research,
14 methods of analysis, research results, and
15 such other information as the Institute de-
16 termines appropriate);

17 “(v) the identity of investigators con-
18 ducting such research and any conflicts of
19 interest of such investigators; and

20 “(vi) any progress reports the Insti-
21 tute determines appropriate.

22 “(B) Public comments submitted during
23 each of the public comment periods under para-
24 graph (1)(A).

1 “(C) Bylaws, processes, and proceedings of
2 the Institute, to the extent practicable and as
3 the Institute determines appropriate.

4 “(D) Not later than 90 days after receipt
5 by the Institute of a relevant report or research
6 findings, appropriate information contained in
7 such report or findings.

8 “(4) CONFLICTS OF INTEREST.—The Institute
9 shall—

10 “(A) in appointing members to an advisory
11 panel under subsection (d)(5) and the method-
12 ology committee under subsection (d)(6), and in
13 selecting individuals to contribute to any peer-
14 review process under subsection (d)(7) and for
15 employment as executive staff of the Institute,
16 take into consideration any conflicts of interest
17 of potential appointees, participants, and staff;
18 and

19 “(B) include a description of any such con-
20 flicts of interest and conflicts of interest of
21 Board members in the annual report under sub-
22 section (d)(11), except that, in the case of indi-
23 viduals contributing to any such peer review
24 process, such description shall be in a manner

1 such that those individuals cannot be identified
2 with a particular research project.

3 “(j) RULES.—

4 “(1) GIFTS.—The Institute, or the Board and
5 staff of the Institute acting on behalf of the Insti-
6 tute, may not accept gifts, bequeaths, or donations
7 of services or property.

8 “(2) ESTABLISHMENT AND PROHIBITION ON
9 ACCEPTING OUTSIDE FUNDING OR CONTRIBU-
10 TIONS.—The Institute may not—

11 “(A) establish a corporation other than as
12 provided under this section; or

13 “(B) accept any funds or contributions
14 other than as provided under this part.

15 “(k) RULES OF CONSTRUCTION.—

16 “(1) COVERAGE.—Nothing in this section shall
17 be construed—

18 “(A) to permit the Institute to mandate
19 coverage, reimbursement, or other policies for
20 any public or private payer; or

21 “(B) as preventing the Secretary from cov-
22 ering the routine costs of clinical care received
23 by an individual entitled to, or enrolled for, ben-
24 efits under title XVIII, XIX, or XXI in the case
25 where such individual is participating in a clin-

1 ical trial and such costs would otherwise be cov-
 2 ered under such title with respect to the bene-
 3 ficiary.

4 “(2) REPORTS AND FINDINGS.—None of the re-
 5 ports submitted under this section or research find-
 6 ings disseminated by the Institute shall be construed
 7 as mandates, guidelines, or recommendations for
 8 payment, coverage, or treatment.

9 “TRUST FUND TRANSFERS TO COMPARATIVE
 10 EFFECTIVENESS RESEARCH TRUST FUND

11 “SEC. 1182. (a) IN GENERAL.—The Secretary shall
 12 provide for the transfer, from the Federal Hospital Insur-
 13 ance Trust Fund under section 1817 and the Federal Sup-
 14 plementary Medical Insurance Trust Fund under section
 15 1841, in proportion (as estimated by the Secretary) to the
 16 total expenditures during such fiscal year that are made
 17 under title XVIII from the respective trust fund, to the
 18 Comparative Effectiveness Research Trust Fund (referred
 19 to in this section as the ‘CERTF’) under section 9511
 20 of the Internal Revenue Code of 1986, the following:

21 “(1) For fiscal year 2012, an amount equal to
 22 50 cents multiplied by the average number of indi-
 23 viduals entitled to benefits under part A, or enrolled
 24 under part B, of title XVIII during such fiscal year.

25 “(2) For each of fiscal years 2013, 2014, 2015,
 26 2016, 2017, and 2018, an amount equal to \$1 mul-

1 multiplied by the average number of individuals entitled
 2 to benefits under part A, or enrolled under part B,
 3 of title XVIII during such fiscal year.

4 “(b) ADJUSTMENTS FOR INCREASES IN HEALTH
 5 CARE SPENDING.—In the case of any fiscal year begin-
 6 ning after September 30, 2013, the dollar amount in effect
 7 under subsection (a)(2) for such fiscal year shall be equal
 8 to the sum of such dollar amount for the previous fiscal
 9 year (determined after the application of this subsection),
 10 plus an amount equal to the product of—

11 “(1) such dollar amount for the previous fiscal
 12 year, multiplied by

13 “(2) the percentage increase in the projected
 14 per capita amount of National Health Expenditures
 15 from the calendar year in which the previous fiscal
 16 year ends to the calendar year in which the fiscal
 17 year involved ends, as most recently published by the
 18 Secretary before the beginning of the fiscal year.”.

19 (b) COORDINATION WITH PROVIDER EDUCATION
 20 AND TECHNICAL ASSISTANCE.—Section 1889(a) of the
 21 Social Security Act (42 U.S.C. 1395zz(a)) is amended by
 22 inserting “and to enhance the understanding of and utili-
 23 zation by providers of services and suppliers of research
 24 findings disseminated by the Health Care Comparative Ef-

fectiveness Research Institute established under section 1181” before the period at the end.

(c) COMPARATIVE EFFECTIVENESS RESEARCH TRUST FUND; FINANCING FOR TRUST FUND.—

(1) ESTABLISHMENT OF TRUST FUND.—

(A) IN GENERAL.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to establishment of trust funds) is amended by adding at the end the following new section:

“SEC. 9511. COMPARATIVE EFFECTIVENESS RESEARCH TRUST FUND.

“(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the ‘Comparative Effectiveness Research Trust Fund’ (hereafter in this section referred to as the ‘CERTF’), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

“(b) TRANSFERS TO FUND.—

“(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

“(A) For fiscal year 2009, \$5,000,000.

“(B) For fiscal year 2010, \$25,000,000.

“(C) For fiscal year 2011, \$75,000,000.

1 “(D) For fiscal year 2012—

2 “(i) an amount equivalent to the net
3 revenues received in the Treasury from the
4 fees imposed under subchapter B of chap-
5 ter 34 (relating to fees on health insurance
6 and self-insured plans) for such fiscal year;
7 and

8 “(ii) \$75,000,000.

9 “(E) For each of fiscal years 2013, 2014,
10 2015, 2016, 2017, and 2018—

11 “(i) an amount equivalent to the net
12 revenues received in the Treasury from the
13 fees imposed under subchapter B of chap-
14 ter 34 (relating to fees on health insurance
15 and self-insured plans) for such fiscal year;
16 and

17 “(ii) \$75,000,000.

18 The amounts appropriated under subparagraphs
19 (A), (B), (C), (D)(ii), and (E)(ii) shall be trans-
20 ferred from the general fund of the Treasury, from
21 funds not otherwise appropriated.

22 “(2) TRUST FUND TRANSFERS.—In addition to
23 the amounts appropriated under paragraph (1),
24 there shall be credited to the CERTF the amounts

1 transferred under section 1182 of the Social Secu-
2 rity Act.

3 “(3) LIMITATION ON TRANSFERS TO CERTF.—

4 No amount may be appropriated or transferred to
5 the CERTF on and after the date of any expendi-
6 ture from the CERTF which is not an expenditure
7 permitted under this section. The determination of
8 whether an expenditure is so permitted shall be
9 made without regard to—

10 “(A) any provision of law which is not con-
11 tained or referenced in this chapter or in a rev-
12 enue Act, and

13 “(B) whether such provision of law is a
14 subsequently enacted provision or directly or in-
15 directly seeks to waive the application of this
16 paragraph.

17 “(c) TRUSTEE.—The Secretary of Health and
18 Human Services shall be a trustee of the CERTF.

19 “(d) EXPENDITURES FROM FUND.—Amounts in the
20 CERTF are available, without further appropriation, to
21 the Health Care Comparative Effectiveness Research In-
22 stitute established by section 2(a) of the Comparative Ef-
23 fectiveness Research Act of 2008 for carrying out part D
24 of title XI of the Social Security Act (as in effect on the

1 date of enactment of the Comparative Effectiveness Re-
2 search Act of 2008).

3 “(e) NET REVENUES.—For purposes of this section,
4 the term ‘net revenues’ means the amount estimated by
5 the Secretary of the Treasury based on the excess of—

6 “(1) the fees received in the Treasury under
7 subchapter B of chapter 34, over

8 “(2) the decrease in the tax imposed by chapter
9 1 resulting from the fees imposed by such sub-
10 chapter.

11 “(f) TERMINATION.—No amounts shall be available
12 for expenditure from the CERTF after September 30,
13 2018, and any amounts in such Trust Fund after such
14 date shall be transferred to the general fund of the Treas-
15 ury.”.

16 (B) CLERICAL AMENDMENT.—The table of
17 sections for subchapter A of chapter 98 of such
18 Code is amended by adding at the end the fol-
19 lowing new item:

“Sec. 9511. Comparative Effectiveness Research Trust Fund.”.

20 (2) FINANCING FOR FUND FROM FEES ON IN-
21 SURED AND SELF-INSURED HEALTH PLANS.—

22 (A) GENERAL RULE.—Chapter 34 of the
23 Internal Revenue Code of 1986 is amended by
24 adding at the end the following new subchapter:

1 **“Subchapter B—Insured and Self-Insured**
 2 **Health Plans**

“Sec. 4375. Health insurance.

“Sec. 4376. Self-insured health plans.

“Sec. 4377. Definitions and special rules.

3 **“SEC. 4375. HEALTH INSURANCE.**

4 “(a) IMPOSITION OF FEE.—There is hereby imposed
 5 on each specified health insurance policy for each policy
 6 year ending after September 30, 2011, a fee equal to the
 7 product of \$1 (50 cents in the case of policy years ending
 8 during fiscal year 2012) multiplied by the average number
 9 of lives covered under the policy.

10 “(b) LIABILITY FOR FEE.—The fee imposed by sub-
 11 section (a) shall be paid by the issuer of the policy.

12 “(c) SPECIFIED HEALTH INSURANCE POLICY.—For
 13 purposes of this section:

14 “(1) IN GENERAL.—Except as otherwise pro-
 15 vided in this section, the term ‘specified health in-
 16 surance policy’ means any accident or health insur-
 17 ance policy (including a policy under a group health
 18 plan) issued with respect to individuals residing in
 19 the United States.

20 “(2) EXEMPTION FOR CERTAIN POLICIES.—The
 21 term ‘specified health insurance policy’ does not in-
 22 clude any insurance if substantially all of its cov-
 23 erage is of excepted benefits described in section
 24 9832(c).

1 “(3) TREATMENT OF PREPAID HEALTH COV-
2 ERAGE ARRANGEMENTS.—

3 “(A) IN GENERAL.—In the case of any ar-
4 rangement described in subparagraph (B)—

5 “(i) such arrangement shall be treated
6 as a specified health insurance policy, and

7 “(ii) the person referred to in such
8 subparagraph shall be treated as the
9 issuer.

10 “(B) DESCRIPTION OF ARRANGEMENTS.—

11 An arrangement is described in this subpara-
12 graph if under such arrangement fixed pay-
13 ments or premiums are received as consider-
14 ation for any person’s agreement to provide or
15 arrange for the provision of accident or health
16 coverage to residents of the United States, re-
17 gardless of how such coverage is provided or ar-
18 ranged to be provided.

19 “(d) ADJUSTMENTS FOR INCREASES IN HEALTH
20 CARE SPENDING.—In the case of any policy year ending
21 in any fiscal year beginning after September 30, 2013, the
22 dollar amount in effect under subsection (a) for such pol-
23 icy year shall be equal to the sum of such dollar amount
24 for policy years ending in the previous fiscal year (deter-

1 mined after the application of this subsection), plus an
2 amount equal to the product of—

3 “(1) such dollar amount for policy years ending
4 in the previous fiscal year, multiplied by

5 “(2) the percentage increase in the projected
6 per capita amount of National Health Expenditures
7 from the calendar year in which the previous fiscal
8 year ends to the calendar year in which the fiscal
9 year involved ends, as most recently published by the
10 Secretary of Health and Human Services before the
11 beginning of the fiscal year.

12 “(e) TERMINATION.—This section shall not apply to
13 policy years ending after September 30, 2018.

14 **“SEC. 4376. SELF-INSURED HEALTH PLANS.**

15 “(a) IMPOSITION OF FEE.—In the case of any appli-
16 cable self-insured health plan for each plan year ending
17 after September 30, 2011, there is hereby imposed a fee
18 equal to \$1 (50 cents in the case of plan years ending
19 during fiscal year 2012) multiplied by the average number
20 of lives covered under the plan.

21 “(b) LIABILITY FOR FEE.—

22 “(1) IN GENERAL.—The fee imposed by sub-
23 section (a) shall be paid by the plan sponsor.

24 “(2) PLAN SPONSOR.—For purposes of para-
25 graph (1) the term ‘plan sponsor’ means—

1 “(A) the employer in the case of a plan es-
2 tablished or maintained by a single employer,

3 “(B) the employee organization in the case
4 of a plan established or maintained by an em-
5 ployee organization,

6 “(C) in the case of—

7 “(i) a plan established or maintained
8 by 2 or more employers or jointly by 1 or
9 more employers and 1 or more employee
10 organizations,

11 “(ii) a multiple employer welfare ar-
12 rangement, or

13 “(iii) a voluntary employees’ bene-
14 ficiary association described in section
15 501(c)(9),

16 the association, committee, joint board of trust-
17 ees, or other similar group of representatives of
18 the parties who establish or maintain the plan,
19 or

20 “(D) the cooperative or association de-
21 scribed in subsection (c)(2)(F) in the case of a
22 plan established or maintained by such a coop-
23 erative or association.

24 “(c) APPLICABLE SELF-INSURED HEALTH PLAN.—

25 For purposes of this section, the term ‘applicable self-in-

1 sured health plan' means any plan for providing accident
2 or health coverage if—

3 “(1) any portion of such coverage is provided
4 other than through an insurance policy, and

5 “(2) such plan is established or maintained—

6 “(A) by one or more employers for the
7 benefit of their employees or former employees,

8 “(B) by one or more employee organiza-
9 tions for the benefit of their members or former
10 members,

11 “(C) jointly by 1 or more employers and 1
12 or more employee organizations for the benefit
13 of employees or former employees,

14 “(D) by a voluntary employees' beneficiary
15 association described in section 501(c)(9),

16 “(E) by any organization described in sec-
17 tion 501(c)(6), or

18 “(F) in the case of a plan not described in
19 the preceding subparagraphs, by a multiple em-
20 ployer welfare arrangement (as defined in sec-
21 tion 3(40) of Employee Retirement Income Se-
22 curity Act of 1974), a rural electric cooperative
23 (as defined in section 3(40)(B)(iv) of such Act),
24 or a rural telephone cooperative association (as
25 defined in section 3(40)(B)(v) of such Act).

1 “(d) ADJUSTMENTS FOR INCREASES IN HEALTH
 2 CARE SPENDING.—In the case of any plan year ending
 3 in any fiscal year beginning after September 30, 2013, the
 4 dollar amount in effect under subsection (a) for such plan
 5 year shall be equal to the sum of such dollar amount for
 6 plan years ending in the previous fiscal year (determined
 7 after the application of this subsection), plus an amount
 8 equal to the product of—

9 “(1) such dollar amount for plan years ending
 10 in the previous fiscal year, multiplied by

11 “(2) the percentage increase in the projected
 12 per capita amount of National Health Expenditures
 13 from the calendar year in which the previous fiscal
 14 year ends to the calendar year in which the fiscal
 15 year involved ends, as most recently published by the
 16 Secretary of Health and Human Services before the
 17 beginning of the fiscal year.

18 “(e) TERMINATION.—This section shall not apply to
 19 plan years ending after September 30, 2018.

20 **“SEC. 4377. DEFINITIONS AND SPECIAL RULES.**

21 “(a) DEFINITIONS.—For purposes of this sub-
 22 chapter—

23 “(1) ACCIDENT AND HEALTH COVERAGE.—The
 24 term ‘accident and health coverage’ means any cov-
 25 erage which, if provided by an insurance policy,

1 would cause such policy to be a specified health in-
 2 surance policy (as defined in section 4375(c)).

3 “(2) INSURANCE POLICY.—The term ‘insurance
 4 policy’ means any policy or other instrument where-
 5 by a contract of insurance is issued, renewed, or ex-
 6 tended.

7 “(3) UNITED STATES.—The term ‘United
 8 States’ includes any possession of the United States.

9 “(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

10 “(1) IN GENERAL.—For purposes of this sub-
 11 chapter—

12 “(A) the term ‘person’ includes any gov-
 13 ernmental entity, and

14 “(B) notwithstanding any other law or rule
 15 of law, governmental entities shall not be ex-
 16 empt from the fees imposed by this subchapter
 17 except as provided in paragraph (2).

18 “(2) TREATMENT OF EXEMPT GOVERNMENTAL
 19 PROGRAMS.—In the case of an exempt governmental
 20 program, no fee shall be imposed under section 4375
 21 or section 4376 on any covered life under such pro-
 22 gram.

23 “(3) EXEMPT GOVERNMENTAL PROGRAM DE-
 24 FINED.—For purposes of this subchapter, the term
 25 ‘exempt governmental program’ means—

1 “(A) any insurance program established
2 under title XVIII of the Social Security Act,

3 “(B) the medical assistance program es-
4 tablished by title XIX or XXI of the Social Se-
5 curity Act,

6 “(C) any program established by Federal
7 law for providing medical care (other than
8 through insurance policies) to individuals (or
9 the spouses and dependents thereof) by reason
10 of such individuals being—

11 “(i) members of the Armed Forces of
12 the United States, or

13 “(ii) veterans, and

14 “(D) any program established by Federal
15 law for providing medical care (other than
16 through insurance policies) to members of In-
17 dian tribes (as defined in section 4(d) of the In-
18 dian Health Care Improvement Act).

19 “(c) TREATMENT AS TAX.—For purposes of subtitle
20 F, the fees imposed by this subchapter shall be treated
21 as if they were taxes.

22 “(d) NO COVER OVER TO POSSESSIONS.—Notwith-
23 standing any other provision of law, no amount collected
24 under this subchapter shall be covered over to any posses-
25 sion of the United States.”.

1 (B) CLERICAL AMENDMENTS.—

2 (i) Chapter 34 of such Code is amend-
3 ed by striking the chapter heading and in-
4 serting the following:

5 **“CHAPTER 34—TAXES ON CERTAIN**
6 **INSURANCE POLICIES**

“SUBCHAPTER A. POLICIES ISSUED BY FOREIGN INSURERS

“SUBCHAPTER B. INSURED AND SELF-INSURED HEALTH PLANS

7 **“Subchapter A—Policies Issued By Foreign**
8 **Insurers”.**

9 (ii) The table of chapters for subtitle
10 D of such Code is amended by striking the
11 item relating to chapter 34 and inserting
12 the following new item:

“CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES”.

13 **SEC. 3. GAO REPORT ON NATIONAL COVERAGE DETER-**
14 **MINATIONS PROCESS.**

15 Not later than 18 months after the date of enactment
16 of this Act, the Comptroller General of the United States
17 shall submit a report to Congress on the process for mak-
18 ing national coverage determinations (as defined in section
19 1869(f)(1)(B) of the Social Security Act (42 U.S.C.
20 1395ff(f)(1)(B)) under the Medicare program under title
21 XVIII of the Social Security Act. Such report shall include
22 a determination whether, in initiating and conducting such
23 process, the Secretary of Health and Human Services has

1 complied with applicable law and regulations, including re-
2 quirements for consultation with appropriate outside ex-
3 perts, providing appropriate notice and comment opportu-
4 nities to the public, and making information and data
5 (other than proprietary data) considered in making such
6 determinations available to the public and to nonvoting
7 members of any advisory committees established to advise
8 the Secretary with respect to such determinations.

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